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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,713	08/25/2003	Jonathan Stamler	102258.121 US3	9858
759	90 06/21/2005		EXAM	INER
Hollie L. Baker			GHALI, ISIS A D	
HALE AND DORR, LLP 60 State Street			ART UNIT	PAPER NUMBER
Boston, MA 02109			1615	
			DATE MAILED: 06/21/2005	

Please find below and/or attached an Office communication concerning this application or proceeding.

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	Application No.	Applicant(s)				
	10/646,713	STAMLER ET AL.				
Office Action Summary	Examiner	Art Unit				
	Isis Ghali	1615				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1) Responsive to communication(s) filed on <u>3/8/6</u>						
	is action is non-final.	ı				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims						
4)⊠ Claim(s) <u>1-35</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-35</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or election requirement.						
Application Papers						
9)☐ The specification is objected to by the Examiner.						
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
11)☐ The proposed drawing correction filed on is: a)☐ approved b)☐ disapproved by the Examiner.						
If approved, corrected drawings are required in rep	•					
12)☐ The oath or declaration is objected to by the Examiner.						
Priority under 35 U.S.C. §§ 119 and 120						
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) ☐ All b) ☐ Some * c) ☐ None of:						
1. Certified copies of the priority documents						
2. Certified copies of the priority documents	s have been received in Application	on No				
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the confided copies not received.						
* See the attached detailed Office action for a list of the certified copies not received.  14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).						
a) ☐ The translation of the foreign language provisional application has been received.						
15)⊠ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.						
Attachment(s)						
1) ⊠ Notice of References Cited (PTO-892) 2) ☑ Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) ☑ Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>12</u>	5) Notice of Informal P	r (PTO-413) Paper No(s) Patent Application (PTO-152)				

Part of Paper No. 20050603

#### **DETAILED ACTION**

The receipt is acknowledged of applicants' IDS, filed 12/06/2004; and terminal disclaimer and amendment, both filed 03/08/2005.

Claims 1-35 are included in the prosecution.

#### Terminal Disclaimer

1. The terminal disclaimer filed on 03/08/2005 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US 6,471,978; US 6,352,709; US 6,255,277; US 6,174,539; and US 6,087,479 has been reviewed and is accepted. The terminal disclaimer has been recorded.

### Claim Rejections - 35 USC § 112

- 2. The following is a quotation of the first paragraph of 35 U.S.C. 112:
  - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 3. Claims 1-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification lacks description to each of the claimed nitrate that are selected from the group consisting of polypeptide; amino

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71,700111.01 11411.2011 10,010,11

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acids; sugar; oligonucleotide; branched or unbranched, saturated or unsaturated aliphatic hydrocarbon; aromatic hydrocarbon; or heterocyclic compounds. The claims encompass wide classes of compounds that have unrelated structure that all used to inhibit platelets deposition. The specification does not describe method for inhibiting platelets deposition using reasonable number of representative examples of each of claimed classes in order to assure one skilled in the art that the compounds fall within the scope of the claim possess the alleged activity.

- 4. The following is a quotation of the second paragraph of 35 U.S.C. 112:
  The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 5. Claims 1-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. In the present instance, the claims recite the broad range "heterocyclic compounds" and the narrower range "sugar".

## Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 7. Claims 1-3, 8-10, 15-17, 22-24, and 29-31 rejected under 35 U.S.C. 102(a) as being anticipated by Groves et al.

Groves et al. disclosed that nitroglycerin inhibits platelets aggregation on the vascular endothelium (page 596, left column).

8. Claims 1-3, 5, 7-10, 12,14-17, 19, 21-24, 26, 28-31, 33, and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Loscalso.

Loscalso disclosed that nitroglycerin inhibits platelets aggregation, and this function is potentiated by protein (cysteine).

9. Claims 1-3, 8-10, 15-17, 22-24, and 29-31 are rejected under 35 U.S.C. 102(b) as being anticipated by De Caterina et al.

De Caterina et al. disclosed that nitroglycerin inhibits platelets aggregation in the vessels.

10. Claims 1, 2, 4, 8, 9, 11, 15, 16, 18, 22, 23, 25, 29, 30, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Ambrosioni et al.

Ambrosioni et al. disclose the use of ACE inhibitors for treating ischemic heart disease due to their suppressive action on platelets aggregation.

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11. Claims 1-3, 5, 6, 8-10, 12, 13, 15-17, 19, 20, 22-24, 26, 27, 29-31, 33 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Stamler et al.

Stamler et al. disclosed the synergistic disaggregation of platelets by prostaglandin and nitroglycerin.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali Examiner Art Unit 1615

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